



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; comment request (30-Day FRN):

The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the Federal Register on December 6, 2012 (Vol. # 77, p. 72871) and allowed 60-days for public comment. No public comments have been received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget, at OIRA_submission@omb.eop.gov or by fax to 202-395-6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Jane Hoppin, Sc.D., Epidemiology Branch, National Institute of

Environmental Health Sciences, NIH, 111 T.W. Alexander Drive, PO Box 12233, MD A3-05, Research Triangle Park, NC 27709, or call non-toll-free number 919-541-7622, or e-mail your request, including your address to: hoppin1@niehs.nih.gov.

Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

PROPOSED COLLECTION: The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Disease Among Men and Women in Agriculture, 0925-0406, Expiration Date 5/31/2013 – REVISION - National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this information collection is to continue and complete updating the occupational and environmental exposure information as well as medical history information for licensed pesticide applicators and their spouses enrolled in the Agricultural Health Study. This represents a request to complete phase IV (2013-2015) of the study and to continue and complete the buccal cell collection and the Study of Biomarkers of Exposures and Effects in Agriculture (BEEA). The primary objectives of the study are to determine the health effects resulting from occupational and environmental exposures in the agricultural environment. The phase IV follow up data will be collected by using one of three methods of the cohort member's choosing: self-administered computer assisted web survey (CAWI); self-administered paper-and-pen (Paper/pen); or an interviewer administered computer assisted telephone interview (CATI). Proxy interviews for those cohort members unable to complete the follow up will be completed by using one of the

three methods as well. Secondary objectives include evaluating biological markers that may be associated with agricultural exposures and risk of certain types of cancer.

Questionnaire data will be collected by using computer assisted telephone interview (CATI) and in-person interview (CAPI) systems for telephone screeners and home visit interviews, respectively. Some respondents will also be asked to participate in the collection of biospecimens including blood, urine, and buccal cells (loose cells from the respondent's mouth). The findings will provide valuable information concerning the potential link between agricultural exposures and cancer and other chronic diseases among agricultural Health Study cohort members, and this information may be generalized to the entire agricultural community.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 10,465.

Estimated Annualized Burden Hours

Table A.12-1 ESTIMATES ANNUALIZED BURDEN HOURS					
Type of Respondent	Form	Number of Respondents	Number of Responses per Respondent	Average Time Per Response (in hours)	Total Annual Burden Hour
Private and Commercial Applicators and Spouses	Reminder, Missing, and Damaged Scripts for Buccal Cell	100	1	5/60	8
Private Applicators	BEEA CATI Screener	480	1	20/60	160
Private Applicators	BEEA Home Visit CAPI, Blood, & Urine x 1	160	1	30/60	80
Private Applicators	BEEA Schedule Home Visit Script	20	3	5/60	5
Private Applicators	BEEA Home Visit CAPI, Blood, & Urine x 3	20	3	30/60	30
Private Applicators	Paper/pen, CAWI or CATI	13,855	1	25/60	5,773
Spouses	Paper/pen, CAWI or CATI	10,201	1	25/60	4,250
Proxy	Paper/pen, CAWI or CATI	635	1	15/60	159
Total					10,465

Dated: January 30, 2013

Vivian Horovitch-Kelley

NCI Project Clearance Liaison

NCI, NIH

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